

TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A SUBMISSION UNDER 35 U.S.C. 371		ATTORNEY'S DOCKET NUMBER 09600-00031-US U.S. APPLICATION NO. (U.S. Patent and Trademark Office) 10/538223
INTERNATIONAL APPLICATION NO. PCT/EP2003/012675	INTERNATIONAL FILING DATE 13 November 2003	PRIORITY DATE CLAIMED 9 December 2002
TITLE OF INVENTION FORMULATION WHICH CAN BE ADMINISTERED GASTROINTESTINALLY, AND THE USE THEREOF		
APPLICANT(S) FOR DO/EO/US Heinz Schneider		

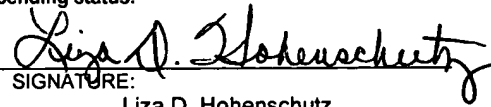
Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. ☒ This is a **FIRST** submission of items concerning a submission under 35 U.S.C. 371.
2. ☐ This is a **SECOND** or **SUBSEQUENT** submission of items concerning a submission under 35 U.S.C. 371.
3. ☐ This is an express request to begin national examination procedures (35 U.S.C. 371 (f)). The submission must include items (5), (6), (9) and (21) indicated below.
4. ☒ The US has been elected (Article 31).
5. ☒ A copy of the International Application as filed (35 U.S.C. 371 (c)(2))
 - a. ☒ is attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ has been communicated by the International Bureau.
 - c. ☐ is not required, as the application was filed in the United States Receiving Office (RO/US).
6. ☒ An English language translation of the International Application as filed (35 U.S.C. 371 (c)(2)).
 - a. ☒ is attached hereto.
 - b. ☐ has been previously submitted under 35 U.S.C. 154(d)(4).
7. ☐ Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371 (c)(3))
 - a. ☐ are attached hereto (required only if not communicated by the International Bureau).
 - b. ☐ have been communicated by the International Bureau.
 - c. ☐ have not been made; however, the time limit for making such amendments has NOT expired.
 - d. ☐ have not been made and will not be made.
8. ☐ An English language translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371 (c)(3)).
9. ☐ An oath or declaration of the inventor(s) (35 U.S.C. 371 (c)(4)).
10. ☐ An English language translation of the annexes of the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371 (c)(5)).

Items 11 to 20 below concern document(s) or information included:

11. ☒ An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. ☐ An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. ☒ A preliminary amendment.
14. ☒ An Application Data Sheet under 37 CFR 1.76.
15. ☐ A substitute specification.
16. ☐ A power of attorney and/or change of address letter.
17. ☐ A computer-readable form of the sequence listing in accordance with PCT Rule 13ter.2 and 37 CFR 1.821 - 1.825.
18. ☐ A second copy of the published International Application under 35 U.S.C. 154(d)(4).
19. ☐ A second copy of the English language translation of the international application under 35 U.S.C. 154(d)(4).
20. ☒ Other items or information: Form PCT/RO/101, Form PCT/IB/308, Postcard, Certificate of Express Mail

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it displays a valid OMB control number.

U.S. APPLICATION NO. 10/538227		INTERNATIONAL APPLICATION NO. PCT/EP2003/012675		ATTORNEY'S DOCKET NUMBER 09600-00031-US	
The following fees have been submitted				CALCULATIONS	PTO USE ONLY
21.	<input checked="" type="checkbox"/> Basic national fee	\$300		\$ 300.00	
22.	<input checked="" type="checkbox"/> Examination fee				
If International preliminary examination report prepared by USPTO and all claims satisfy provisions of PCT Article 33(1)-(4)				\$ 200.00	
All other situations					
23.	<input checked="" type="checkbox"/> Search fee				
Search fee (37 CFR 1.445(a)(2)) has been paid on the international application to the USPTO as an International Searching Authority				\$ 400.00	
International Search Report prepared and provided to the Office				\$ 400.00	
All other situations				\$ 500.00	
TOTAL OF 21, 22 and 23 =				\$ 900.00	
<input type="checkbox"/> Additional fee for specification and drawings filed in paper over 100 sheets (excluding sequence listing or computer program listing filed in an electronic medium). The fee is \$250 for each additional 50 sheets of paper or fraction thereof.					
Total Sheets	Extra sheets	Number of each additional 50 or fraction thereof (round up to a whole number)	RATE		
16 - 100 =	/50 =		x \$250.00		
Surcharge of \$130.00 for furnishing the oath or declaration later than 30 months from the earliest claimed priority date (37 CFR 1.492 (e)).				\$	
CLAIMS	NUMBER FILED	NUMBER EXTRA	RATE		
Total claims	17 - 20 =	0	x	\$ 0.00	
Independent claims	2 - 3 =	0	x	\$ 0.00	
MULTIPLE DEPENDENT CLAIM(s) (if applicable)				+	\$
TOTAL OF ABOVE CALCULATIONS =				\$ 900.00	
<input type="checkbox"/> Applicant claims small entity status. See 37 CFR 1.27. Fees above are reduced by 1/2.				\$	
SUBTOTAL =				\$ 900.00	
Processing fee of \$130.00 for furnishing the English translation later than 30 months from the earliest claimed priority date (37 CFR 1.492 (f)).				+	\$
TOTAL NATIONAL FEE =				\$ 900.00	
Fee for recording the enclosed assignment (37 CFR 1.21 (h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). \$40.00 per property				+	\$
TOTAL FEES ENCLOSED =				\$ 900.00	
				Amount to be refunded:	\$
				Amount to be charged:	\$
<p>a. <input type="checkbox"/> A check in the amount of \$ _____ to cover the above fees is enclosed.</p> <p>b. <input checked="" type="checkbox"/> Please charge my Deposit Account No. <u>03-2775</u> in the amount of \$ <u>900.00</u> to cover the above fees. A duplicate copy of this sheet is enclosed.</p> <p>c. <input checked="" type="checkbox"/> The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. <u>03-2775</u>. A duplicate copy of this sheet is enclosed.</p> <p>d. <input type="checkbox"/> Fees are to be charged to a credit card. WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.</p> <p>NOTE: Where an appropriate time limit under 37 CFR 1.495 has not been met, a petition to revive (37 CFR 1.137 (a) or (b)) must be filed and granted to restore the International Application to pending status.</p> <p>SEND ALL CORRESPONDENCE TO:</p> <div style="text-align: right; margin-right: 50px;">  SIGNATURE: Liza D. Hohenschutz NAME </div> <div style="display: flex; justify-content: space-between; margin-top: 20px;"> <div>CUSTOMER NUMBER: 23416</div> <div style="text-align: right;"> 33,712 REGISTRATION NUMBER <u>June 9, 2005</u> </div> </div>					

10/538223

JC17 Rec'd PCT/PTO 09 JUN 2005

Application No. (if known): Not Yet Assigned

Attorney Docket No.: 09600-00031-US

Title: Formulation Which Can Be Administered Gastrointestinally, and the Use Thereof

Certificate of Express Mailing Under 37 CFR 1.10

I hereby certify that this correspondence is being deposited with the United States Postal Service as Express Mail, Airbill No. EV622756708US in an envelope addressed to:

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Amy L. Hamm

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Telephone Number

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Transmittal Letter to the United States Designated-Elected Office
Fee Transmittal
Application Data Sheet
Copy of International application PCT/EP2003/012675 with search report attached
Form PCT/RO/101
Form PCT/IB/308
English language translation of International application
PCT/EP2003/012675
Information Disclosure Statement, PTO SB08, with references
Preliminary Amendment
Postcard
Charge \$900.00 to deposit account 03-2775